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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,988	07/07/2004	Uri Meir	26235	3129
20529	7590	10/26/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER SAUCIER, SANDRA E	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,988	Applicant(s) MEIR, URL	
	Examiner Sandra Saucier	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78,98-115 and 119-123 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78,98-115 and 119-123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 78, 98-115, 119-123 are pending and are under examination.

Claim Rejections – 35 USC § 112

Claims 78, 98-115, 119-123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims now state that “biological matter” is the subject of the freezing/thawing protocol. However, biological matter includes tissues and organs. The specification on page 4, limits the original description of “sample” to be cells or group of cells or bodily fluids or any constituents thereof. The examples are all drawn to semen. This appears to be a broadening of the original specification to include organs such as liver, brain, lungs, etc. or tissue such as skin, valves, blood vessels, etc..

Claim Rejections – 35 USC § 103

Claims 78, 98-115, 119-123 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,873,254 [IDS].

The claims are directed to a method for changing the temperature of a sample comprising:

- (i) changing the temperature of the sample by subjecting it to a temperature gradient from an initial to an intermediate temperature,
- (ii) subjecting the sample to the intermediate temperature until the sample uniformly reaches the intermediate temperature,
- (iii) changing the temperature of the sample until it reaches a final temperature, wherein the sample exceeds 0.5 cm in at least one cross section and wherein the initial, intermediate and final temperatures are different and all progress in either a higher or lower sequence from one another.

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US 5,873,254 teaches a method of changing the temperature of a sample comprising: subjecting the sample to a temperature gradient to change the temperature of the sample from an initial temperature to an intermediate temperature, held at the constant intermediate temperature, then changing to a final temperature (col. 5, ls. 40-60, col. 6). The temperature is a constant -7C as the sample moves through block 14. This corresponds to maintaining the temperature by pausing the sample. Whether the temperature is maintained at an intermediate level by pausing the sled or having the block uniformly the same intermediate temperature as the sled moves through appears to be an element of experimental design because the result is the same, i.e. maintenance of the same temperature in the sample for a period of time.

The reference lacks the stipulation of the size of the sample as exceeding 0.5cm in each of two mutually perpendicular cross-sections.

In the generic description of the invention (Summary of Invention), no limitation as to the size of the sample is described. Thus, the generic description is non-limiting with regard to size of sample.

While the size of the sample in the exemplification is ABOUT 1cm X 1cm x 0.5mm (col. 6, l. 15), use of the term "about" permits a variation of undefined range around this measurement. Please see MPEP 2144 IV A where it is stated that changes in size, shape or sequence of adding ingredients is *prima facie* obvious. Mere scaling up of a prior art process is not sufficiently patentably distinguish over the art in the absence of other evidence.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions/variations in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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Response to Arguments

Applicant's arguments filed 8/14/07 have been fully considered but they are not persuasive.

Applicant argues that in small samples, the outer and inner zones change their temperatures simultaneously. This is not true. Even the smallest of samples, if the temperature change is applied from one side, will have a temperature gradient across the sample. While the temperature gradient may be very brief, until equilibration is established, there will still be one. The rate of temperature change is always limited by the rate of heat transfer across the sample regardless of sample size.

Applicant argues that it is irrelevant whether the generic description of the prior art is or is not limited to the size of the sample. This is unpersuasive. If the prior art was limited to the size of the sample in the generic portion of the specification, it might not be applicable to the instant claims. That it is not limited, means that the generic portion of the disclosure encompasses the instant claimed method, i. e., the instant sample size. This appears to the examiner to be a relevant distinction.

Applicant urges that it is relevant that the exemplifications of the prior art are drawn to samples which have rectangular cross-sections of about 1 cm X 2 mm. However, a prior art reference is good for all that it teaches including the limitations or lack thereof in the generic portion of the specification and is not limited to the narrower teaching in the exemplifications. Also, the claimed device in the prior art reference has no size limitations concerning the sample to be frozen, or the capacity of the apparatus; thus, applicants arguments regarding the size limitations of the sample with regard to the prior art are not persuasive in the absence of evidence to the contrary.

Applicants assert that '254 does not teach or suggest a sample having at least one cross-section in which the outer zone changes its temperature quicker than its inner zone. This is not persuasive because if the temperature

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change is applied from the outside of a sample, the inner temperature will equilibrate with the outer temperature at a rate which is limited by the heat transfer rate of the sample. This is true no matter what the size of the sample. This is due the thermodynamics of heat transfer during conduction and is dependent on the thermal conductivity of the sample, $k = Q/t \times L/A \times \Delta T$, where k is the thermal conductivity constant, Q is the quantity of heat, t is the time, L is the thickness, A is the surface area and ΔT is the change in temperature. Please notice that all samples have thickness, therefore have positive rates of heat transfer. Only if the sample has no dimensions is heat transfer infinitely large and therefore, truly instantaneous.

Objective evidence of unexpected results will be carefully considered upon presentation.

Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the **ORIGINAL** disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting

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claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
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